[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development and Commercialization of Cancer Immunotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR Part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Midissia Therapeutics ("MIDISSIA") located in San Francisco, California, USA.

Intellectual Property

United States Provisional Patent Application No. 60/476,467, filed June 5, 2003, entitled "Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment" [HHS Reference No. E-116-2003/0-US-01]; International Patent Application No. PCT/US2004/17574 filed June 2, 2004 entitled "Immunogenic Peptides and Peptide Derivatives or The Treatment of Prostate And Breast Cancer Treatment" [HHS Reference No. E-116-2003/0-PCT-02]; United States Patent

No.7,541,035, issued June 2, 2009, entitled “Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment” [HHS Reference No. E-116-2003/0-US-03];United States Patent No. 8,043,623, issued 25 Oct 2011, entitled “Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment” [HHS Reference No. E-116-2003/0-US-04]; United States Provisional Patent Application No. 61/915,948, filed December 13, 2013, entitled “Multi-Epitope TARP Peptide Vaccine and Uses Thereof” [HHS Reference No. E-047-2014/0-US-01]; International Patent Application No. PCT/US2014/070144 filed December 12, 2014 entitled “Multi-Epitope TARP Peptide Vaccine and Uses Thereof” [HHS Reference No. E-047-2014/0-PCT-02]; and all continuation applications, divisional applications and foreign counterpart applications claiming priority to the US provisional application no. 61/915, 948 and U.S. Provisional Application No. 62/248,964 filed October 30, 2015 titled “Compositions and Methods for the Treatment of HER2-Expressing Solid Tumors” [HHS Reference No. E-187-2015/0-US-01] and continuation applications, divisional applications and foreign counterpart applications claiming priority to the US provisional application no. 62/248,964.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following:

1) Development and commercialization of a therapeutic cancer vaccine specifically in combination with Licensee's proprietary or exclusively in-licensed vectors/adjuvants and ME-TARP;
2) Development and commercialization of a combination product using Licensee's proprietary or exclusively in-licensed check point inhibitor with Ad-Her2 and ME-TARP vaccine within the Licensed Patent Rights.

DATE: Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESS: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Sabarni K. Chatterjee, Ph.D., M.B.A. Senior Licensing and Patenting Manager, NCI Technology Transfer Center, 9609 Medical Center Drive, RM 1E530 MSC 9702, Bethesda, MD 20892-9702 (for business mail), Rockville, MD 20850-9702 Telephone: (240)-276-5530; Facsimile: (240)-276-5504E-mail: chatterjeesa@mail.nih.gov.

SUPPLEMENTARY INFORMATION: This invention concerns the identification of immunogenic peptides within TARP, and their use to create an anti-cancer immune response in patients. By introducing these peptides into a patient, an immune response against these cancer cells can be initiated by the peptides, resulting in treatment of the

cancer. A phase I clinical trial in stage D0 prostate cancer patients is nearing completion. Initial results indicate a statistically significant decrease in the slope of PSA for 48 weeks after vaccination.

Additionally, a novel vaccine candidate using recombinant adenoviruses expressing the extracellular (EC) and transmembrane (TM) domains of human HER2 (HER2ECTM) are also being developed that is within the scope of the field of use licensed to Midissia. The recombinant adenovirus expresses a chimeric fiber protein having the adenovirus type 35 (Ad5) shaft and knob domains, which facilitates transduction of human dendritic cells by the recombinant HER2ECTM expressing adenovirus. The vaccine candidate, namely, AdHer2ECTM) can potentially to treat patients with Her2 expressing tumors. Clinical studies with this adenovirus based vaccine is currently being planned.

Both technologies have the potential of being developed into a vaccine for several cancer indications or for the treatment of any cancer associated with increased or preferential expression of TARP and Her 2/neu.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR Part 404.7. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR Part 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and

objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

March 16, 2016 _____

Date

Richard U. Rodriguez, M.B.A.

Associate Director

Technology Transfer Center

National Cancer Institute

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